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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,012	08/16/2000	William Russell Kanz	PA036	6843

23710 7590 03/20/2003

A-MED SYSTEMS INC
2491 BOATMAN AVENUE
WEST SACRAMENTO, CA 95691

EXAMINER

BIANCO, PATRICIA

ART UNIT PAPER NUMBER

3762

DATE MAILED: 03/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,012

Applicant(s)

KANZ ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of **Group I, claims 1-13**, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims **14-17 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

4. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/313,268, filed 5/18/99. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application

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data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a).

For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37

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CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Applicant should update the first paragraph of the specification to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

5. The attempt to incorporate subject matter into this application by reference to one or more U. S. Patent Application is improper because applicant has not provided a U. S. serial number for the applications and/or a U. S. Patent Number (if the patent has issued). The incorporation by reference of nonessential subject matter is to provide the public with a patent disclosure that minimizes the public's burden to search for and obtain the documents incorporated by reference, which may not be readily available. Proper indication of the referenced application(s) should include an identification of the

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application serial number, for example "Application No. _____" (see MPEP 608.01(p)). Applicant has attempted to incorporate patent applications to 08/891,456 (see page 10, lines 20-23) and 60/178,479 (see page 11, lines 11-13), however, their status is not given.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 5, 9-11 & 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Reich et al. (4,135,253). Reich et al. (hereafter Reich) discloses a centrifugal blood pump (10) having a main inlet port (12), a main outlet port (14) and supplemental ports, inflow (30) and outflow (32), all operably connected to the blood pump. Reich discloses that the blood pump is used in a method of pumping blood from a heart into and out of the main ports. Reich also discloses that the blood flows into the pump via a cannula and out via a tube. It is inherent that the ports will be connected to flow tubing, i.e. catheters or cannulae, that are capable of being adapted to supply blood to a vein or artery or adapted to be positioned within an artery or the aorta.

7. Claims 1-7, 9-11 & 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Izraelev (5,685,700). Izraelev discloses a blood pump (10) having a pair of inlet

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ports (16 & 17) and a pair of outlet ports (18 & 19). Thus, the supplemental port may be either an inflow or outflow port. Izraelev discloses that the pump may have the outlets coupled to the aorta. With respect to the ports connected to catheters and/or cannulae, it is inherent that the ports will be connected to flow tubing, i.e. catheters or cannulae, such that blood is delivered from the heart to the pump and that these catheters and/or cannula are capable of being adapted to supply blood to a vein or artery or adapted to be positioned within an artery or the aorta.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. in view of Runge (5,688,245). Reich et al. discloses the invention substantially as claimed, see rejection supra. Reich, however, fails to disclose specifically that the supplemental port have a valve. Runge discloses a bypass system including a blood pump and tubing or cannula in communication with the pump. Runge further teaches that inflow and outflow conduits may include a valve for control of fluid therethrough. It would have been obvious at the time of the invention to modify the system of Reich by including valves in at least the tubing in communication with the supplemental port since it was well known at the time to use valved tubing to control fluid into and out of blood pumps and bypass systems.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Izraelev in view of Runge (5,688,245). Izraelev discloses the invention substantially as claimed, see rejection supra. Izraelev, however, fails to disclose specifically that the supplemental port have a valve. Runge discloses a bypass system including a blood pump and tubing or cannula in communication with the pump. Runge further teaches that inflow and outflow conduits may include a valve for control of fluid therethrough. It would have been obvious at the time of the invention to modify the system of Izraelev by including valves in at least the tubing in communication with the supplemental port since it was well known at the time to use valved tubing to control fluid into and out of blood pumps and bypass systems.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. in view of Afzal et al.(6,387,323). Reich et al. discloses the invention substantially as claimed, see rejection supra. Reich, however, fails to disclose specifically that the blood pump is connected to an oxygenator. Afzal et al. (hereafter Afzal) discloses a system having a blood pump in communication with a blood oxygenator to provide blood oxygenation while a patient is on cardiopulmonary bypass. It would have been obvious at the time of the invention to couple the pump of Reich to a blood oxygenator since it was well known at the time for cardiopulmonary bypass systems to have a pump coupled to an oxygenator to supply deoxygenated blood to the oxygenator for oxygenation and subsequently delivering the oxygenated blood back to the patient while the heart is on bypass to prevent the vital organs of the patient to become ischemic thereby preventing any damage during the bypass procedure.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Izraelev in view of Afzal et al.(6,387,323). Izraelev discloses the invention substantially as claimed, see rejection supra. Izraelev, however, fails to disclose specifically that the blood pump is connected to an oxygenator. Afzal et al. (hereafter Afzal) discloses a system having a blood pump in communication with a blood oxygenator to provide blood oxygenation while a patient is on cardiopulmonary bypass. It would have been obvious at the time of the invention to couple the pump of Izraelev to a blood oxygenator since it was well known at the time for cardiopulmonary bypass systems to have a pump coupled to an oxygenator to supply deoxygenated blood to the oxygenator

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for oxygenation and subsequently delivering the oxygenated blood back to the patient while the heart is on bypass to prevent the vital organs of the patient to become ischemic thereby preventing any damage during the bypass procedure.

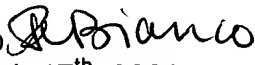
Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clausen et al., Olsen et al., and Kletschka all disclose analogous blood pumps having multiple ports. Richelsoph discloses an artificial heart for pumping blood having multiple inlet and outlet ports. Aboul-Hosn et al. Discloses a pump and cannula system for use in bypass procedures.

13. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco
Patent Examiner
Art Unit 3762

pmb. 
March 17th, 2003